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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,777	12/20/2005	Franciscus Marinus Hendrikus De Groot	0807840.0103	1785
22832 7590 07/09/2008 Kirkpatrick & Lockhart Preston Gates Ellis LLP (FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM) STATE STREET FINANCIAL CENTER One Lincoln Street BOSTON, MA 02111-2950				
EXAMINER KOSACK, JOSEPH R				
ART UNIT 1626		PAPER NUMBER		
NOTIFICATION DATE 07/09/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary

Application No.

10/534,777

Applicant(s)

DE GROOT ET AL.

Examiner

Joseph R. Kosack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 15, 20-30, 35-42, 44 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13, 14, 16-19, 31-34, 45-49 and 51-55 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-55 are pending in the instant application.

Amendments

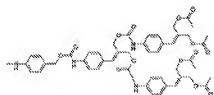
The amendment filed on April 17, 2008 has been acknowledged and has been entered into the application file.

Election/Restrictions

Applicant's election with traverse of a species from claim 43 in the reply filed on April 17, 2008 is acknowledged. The traversal is on the ground(s) that the unity of invention rules were not followed by the Examiner and that the independent claims 1 and 26 are related to a single inventive concept. This is not found persuasive because there is no special technical feature that links the inventions together. In chemistry, the special technical feature needs to be a static core structure that is shared by the genus of claimed compounds. As the genus did not have unity of invention and covered a tremendous number of core structures, the Examiner was forced to ask for the election of species in order to start the Examination.

The requirement is still deemed proper and is therefore made FINAL.

Applicant has made an election of species in the instant case. The search has been expanded to encompass the core structure where $(W-)_{0-6}(X-)_{0-6}C(D)_6$ is



. As claims 8-12, 15, 20-30, 35-42, 44, and 50 do not

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read on the structure searched, they, along with the non searched portions of claims 1-7, 13-14, 16-19, 31-34, 43, 45-49, and 51-55 are withdrawn from further consideration by the Examiner as being drawn to a non-elected invention, 37 CFR 1.142(b).

Priority

The claim to priority as a 371 filing of PCT/NL03/00804 filed on November 14, 2003, which claims priority to PCT/NL02/00732 filed on November 14, 2002 is acknowledged in the instant application. Applicant is asked to place the continuity data in the first line of the specification in response to this action. Additionally, the Applicant is asked to clarify whether to PCT/NL02/00732 is to be considered a foreign application or an international application designating the United States as no information about states designated can be gleaned from the priority document submitted.

Information Disclosure Statement

The Information Disclosure Statements filed on December 20, 2005; May 1, 2006; and April 17, 2008 have been considered by the Examiner.

Claim Objections

Claims 1-7, 13-14, 16-19, 31-34, 43, 45-49, and 51-55 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-7, 13-14, 16-19, 31-34, 45-49, and 51-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, compounds containing specifiers, self-eliminating multiple release spacers, single release 1,(4 + 2n) electronic cascade spacers, cyclization elimination spacers, spacer systems, reactive moieties and methods of using them are claimed.

Applicant is reminded of the written description guidelines set out by the USPTO in MPEP 2163:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

When a chemical genus is claimed, the written description requirement is normally satisfied with a generic chemical structure that is drawn out such that the core structure is clearly shown. A review of the disclosure contains examples (claim 43) which only show an extremely small and related subset and not the large and extensive claimed genus. While the genus is described by a generic formula in claim 4, the

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generic formula is not sufficiently detailed to show that the Applicant was in possession of the full scope of the claimed invention at the time of filing. Namely, that there are no definitions of "specifiers", "self-eliminating multiple release spacers", "single release 1,(4 + 2n) electronic cascade spacers", "cyclization elimination spacers", "spacer systems", and "reactive moieties" provided within the specification. Additionally, there is little structure/function data provided to show that the Applicant in fact possessed the entire claimed genus at the time of filing. Therefore, the "representative number of species" standard is used to determine whether the claims are adequately described. MPEP 2163 goes on to describe what a "representative number of species" is:

What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, para. 1.

As the species described in the specification do not cover the entire genus such that it is a representative sample of the genus, the claims do not meet the written description provision of the first paragraph of 35 U.S.C. 112.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "leaving group" in claims 1-7, 13-14, 16-19, 31-34, 45-49, and 51-55 is used by the claim to mean "a drug", while the accepted meaning is "a group that is expelled during a substitution reaction such as halides, sulfonamides, alkoxides, etc...." The term is indefinite because the specification does not clearly redefine the term.

Claims 4-7 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims define V to be either [O] or a specifier, however no definition for [O] is provided in the claims or the specification. Therefore, it is unknown what the metes and bounds of the term [O] are.

Claims 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the

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steps. See MPEP § 2172.01. The omitted steps are: the steps for the diagnostic assay process.

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim contains the acronyms ADEPT, PDEPT, MDEPT, VDEPT, and GDEPT with no definition provided in the claim or the specification. Therefore, it is unknown what the metes and bounds of the claim are.

Claim 52 provides for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to treating a mammal in need thereof but does not state for what the mammal would need treatment. Therefore, it is not known what the metes and bounds of the patient population are and the claim is indefinite.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 52 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

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35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

Claims 1-7, 13-14, 16-19, 31-34, 45-49, and 51-55 are rejected. Claims 1-7, 13-14, 16-19, 31-34, 43, 45-49, and 51-55 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/REI-TSANG SHIAO /

Primary Examiner, Art Unit 1626

/Joseph R Kosack/

Examiner, Art Unit 1626